AIRE-MASTER FOAMING AB HANDSOAP- triclos an liquid Aire-Master of America, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Triclosan.3%

Purpose

Antiseptic

Uses Handwash to help reduce bacteria that potentially can cause disease

Warnings For external use only

Do not use in eyes. In case of eye contact flush thoroughly with water and seek medical attention. **Stop use and ask doctor** if irritation and redness develop and persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions -Wet hands, apply liberal amount of product and rub hands together for 30 seconds.

-Rinse thoroughly.

Other Information -Keep from freezing.

Inactive Ingredients Water, TEA Lauryl Sulfate, Cocamidopropyl Betaine, Cocamide DEA, Glycerin, Fragrance, DMDM Hydantoin, Propylene Glycol, Aloe Barbadensis Leaf Juice.

Questions or Comments? 800-525-0957 www.airemaster.com

Dru	g	Fa	cts

Active Ingredient

Purpose

Indications:

Handwash to help reduce bacteria that potentially can cause disease.

Directions: Wet hands, apply liberal amount of product and rub hands together for 30 seconds. Rinse thoroughly.

Warnings:

- FOR EXTERNAL USE ONLY.
- · Keep away from eyes. In case of eye contact, flush thoroughly with water and then seek medical advice

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- If swallowed, drink large amounts of water and seek medical attention.
- Avoid contact with face and broken skin. If contact occurs, flush with water.
- If irritation develops, discontinue use. If condition persists, consult a physician.
- Keep out of the reach of children.

Note: Keep from freezing.

Other Ingredients:

Water, Sodium Lauryl Sulfate, Cocamide DEA, Cocamidopropyl Betaine, Glycerin, DMDM Hydantoin, Fragrance, Aloe Barbadensis Leaf Juice, Sodium Chloride, Citric Acid.

Questions or Comments? 888-667-6066



Aire-Master of America PO Box 2310 • Nixa, MO 65714 Not tested on animals.

AIRE-MASTER FOAMING AB HANDSOAP

triclosan liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65133-170	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
TRICLOSA	N (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.3 g in 10 mL

Inactive Ingr	redients	
	Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
TRIETHANO LAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTO IN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65133-170- 09	4 in 1 CASE	0 1/0 1/20 16		
1	NDC:65133-170- 01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:65133-170- 02	208198 mL in 1 DRUM; Type 0: Not a Combination Product	0 1/0 1/20 16		
3	NDC:65133-170- 03	946353 mL in 1 CONTAINER; Type 0: Not a Combination Product	0 1/0 1/20 16		
4	NDC:65133-170- 10	24 in 1 CASE	0 1/0 1/20 16		
4	NDC:65133-170- 04	237 mL in 1 BOTTLE; Type 0: Not a Combination Product			
5	NDC:65133-170- 11	12 in 1 CASE	0 1/0 1/20 16		
5	NDC:65133-170- 05	532 mL in 1 BOTTLE; Type 0: Not a Combination Product			
6	NDC:65133-170- 12	8 in 1 PACKAGE	0 1/0 1/20 16		
6	NDC:65133-170- 06	1000 mL in 1 POUCH; Type 0: Not a Combination Product			
7	NDC:65133-170- 13	48 in 1 CASE	0 1/0 1/20 16		
7	NDC:65133-170- 07	50 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	0 1/0 1/20 16		

Labeler - Aire-Master of America, Inc. (057897381)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aire-Master of America, Inc.		057897381	manufacture(65133-170)	